



Food and Drug Administration  
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November 23, 2015

GUANGZHOU WONDFO BIOTECH CO., LTD.  
C/O JOE SHIA  
BUSINESS DIRECTOR  
504 EAST DIAMOND AVE. SUITE I  
GAITHERSBURG MD 20877

Re: K152495

Trade/Device Name: Wondfo Propoxyphene Urine Test Cup  
Wondfo Propoxyphene Urine Test DipCard  
Regulation Number: 21 CFR 862.3700  
Regulation Name: Propoxyphene test system  
Regulatory Class: II  
Product Code: JXN  
Dated: August 26, 2015  
Received: September 1, 2015

Dear Mr. Joe Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Courtney H. Lias -S**

Courtney H. Lias, Ph.D.  
Director  
Division of Chemistry and Toxicology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
k152495

Device Name

Wondfo Propoxyphene Urine Test Cup  
Wondfo Propoxyphene Urine Test DipCard

Indications for Use (Describe)

Wondfo Propoxyphene Urine Test is an immunochromatographic assay for the qualitative determination of d-Propoxyphene in human urine at a cutoff concentration of 300 ng/mL. The test is available in a dip card format and a test cup format. It is intended for prescription use and over the counter use. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. The test will yield preliminary positive results when prescription drug d-Propoxyphene is ingested, even at or above therapeutic doses. There is no uniformly recognized cutoff concentration for d-Propoxyphene. It is not intended to distinguish between prescription use or abuse of this drug. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## 510(k) SUMMARY

1. Date: October 27, 2015
2. Submitter: Guangzhou Wondfo Biotech Co., Ltd.  
No.8 Lizhishan Road, Science City, Luogang District, Guangzhou, P.R.  
China 510663
3. Contact person: Joe Shia  
LSI International Inc.  
504 East Diamond Ave., Suite I  
Gaithersburg, MD 20878  
Telephone: 240-505-7880  
Fax: 301-916-6213  
Email: shiajl@yahoo.com
4. Device Name: Wondfo Propoxyphene Urine Test Cup (DipCard)

Classification: Class II

| <b>Product Code</b> | <b>CFR #</b>                              | <b>Panel</b> |
|---------------------|---|--------------|
| JXN                 | 21 CFR, 862.3700 Propoxyphene Test System | Toxicology   |

5. Predicate Devices: K121557  
Wondfo Propoxyphene Urine Test

6. Intended Use:

Wondfo Propoxyphene Urine Test is an immunochromatographic assay for the qualitative determination of d-Propoxyphene in human urine at a cutoff concentration of 300 ng/mL. The test is available in a dip card format and a test cup format. It is intended for prescription use and over the counter use. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. The test will yield preliminary positive results when prescription drug d-Propoxyphene is ingested, even at or above therapeutic doses. There is no uniformly recognized cutoff concentration for d-Propoxyphene. It is not intended to distinguish between prescription use or abuse of this drug. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

7. Device Description:

The Wondfo Propoxyphene Urine Test uses immunochromatographic assays for d-Propoxyphene. The test is a lateral flow system for the qualitative detection of d-Propoxyphene in human urine. The test is the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained.

#### 8. Substantial Equivalence Information

| Item                  | Device   | Predicate – K121557 |
|-----------------------|--|---------------------|
| Indication(s) for use | For the qualitative determination of drugs of abuse in human urine   | Same                |
| Methodology           | Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry. | Same                |
| Results               | Qualitative  | Same                |
| Specimen Type         | Human urine  | Same                |
| Cut Off Values        | d-Propoxyphene: 300ng/ml   | Same                |
| Configurations        | Cup and DipCard  | Same                |
| Conditions for Use    | Over-the-Counter   | Prescription Use    |

#### 9. Test Principle

The Wondfo Propoxyphene Urine Test is a rapid test for the qualitative detection of d-Propoxyphene in urine samples and contains lateral flow chromatographic immunoassays for d-Propoxyphene. Each assay uses a mouse monoclonal anti-drug antibody-dye conjugate, fixed drug-protein conjugates, and anti-mouse IgG polyclonal antibodies coated on the test membranes. When the absorbent end of the test is immersed into a urine sample, the urine is absorbed into the device by capillary action and mixes with the antibody-dye conjugate, flowing across the pre-coated membrane. At analyte concentrations below the target cut-off, antibody-dye conjugates bind to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored test line that indicates a negative result. When analyte concentration is above the cut-off, analyte molecules bind to the antibody-dye conjugate, preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. No colored band shows in the test region, indicating a potentially positive result. A band should form in the control region (C) of the device regardless of the presence of drug or metabolite in the sample.

#### 10. Performance Characteristics

1. Analytical Performance Clearance of candidate device is for addition of OTC claim. See analytical performance in predicate K121557.
2. Comparison Studies See studies in predicate K121557
3. Lay-user study

A lay user study was performed at three intended user sites with 280 lay persons, of which 140 tested for the cup format and another 140 tested dipcard format. They had diverse educational and professional backgrounds and ranged in age from 21 to >50 years. Urine samples were prepared at the following concentrations; -100%, +/-75%, +/-50%, +/-25% of the cut-off by spiking d-Propoxyphene into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers, blind-labeled and randomized. Each participant was provided with the package insert, 1 blind labeled sample and a device. The results are summarized below:

**Comparison between GC/MS and Lay Person Results for Cup Format**

| % of Cutoff         | Number of samples | d-Propoxyphene Concentration by GC/MS (ng/mL) | Lay person results |                 | The percentage of correct results (%) |
|---------------------|-------------------|---|--------------------|-----------------|---------------------------------------|
|                     |                   |   | No. of Positive    | No. of Negative |                                       |
| <b>-100% Cutoff</b> | 20                | 0   | 0                  | 20              | 100                                   |
| <b>-75% Cutoff</b>  | 20                | 75.6  | 0                  | 20              | 100                                   |
| <b>-50% Cutoff</b>  | 20                | 148.3   | 0                  | 20              | 100                                   |
| <b>-25% Cutoff</b>  | 20                | 226.7   | 2                  | 18              | 90.0                                  |
| <b>+25% Cutoff</b>  | 20                | 378.2   | 18                 | 2               | 90.0                                  |
| <b>+50% Cutoff</b>  | 20                | 452.4   | 20                 | 0               | 100                                   |
| <b>+75% Cutoff</b>  | 20                | 523.1   | 20                 | 0               | 100                                   |

**Comparison between GC/MS and Lay Person Results for DipCard Format**

| % of Cutoff         | Number of samples | d-Propoxyphene Concentration by GC/MS (ng/mL) | Lay person results |                 | The percentage of correct results (%) |
|---------------------|-------------------|---|--------------------|-----------------|---------------------------------------|
|                     |                   |   | No. of Positive    | No. of Negative |                                       |
| <b>-100% Cutoff</b> | 20                | 0   | 0                  | 20              | 100                                   |
| <b>-75% Cutoff</b>  | 20                | 75.6  | 0                  | 20              | 100                                   |
| <b>-50% Cutoff</b>  | 20                | 148.3   | 0                  | 20              | 100                                   |
| <b>-25% Cutoff</b>  | 20                | 226.7   | 2                  | 18              | 90.0                                  |
| <b>+25% Cutoff</b>  | 20                | 378.2   | 18                 | 2               | 90.0                                  |
| <b>+50% Cutoff</b>  | 20                | 452.4   | 20                 | 0               | 100                                   |
| <b>+75% Cutoff</b>  | 20                | 523.1   | 20                 | 0               | 100                                   |

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed A Flesch-Kincaid reading

analysis was performed on the package insert and the score revealed a reading grade level of less than 7.

#### 4. Clinical Studies

Not applicable.

#### 11. Conclusion

Based on the test principle and performance characteristics of the device, it's concluded that Wondfo Propoxyphene Urine Test is substantially equivalent to the predicate.